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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/533,827	05/03/2005	Michael Birsha Davies	P33145USW	4175

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EXAMINER
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DIXON, ANNETTE FREDRICKA

ART UNIT	PAPER NUMBER
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3771

NOTIFICATION DATE	DELIVERY MODE
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07/17/2008

ELECTRONIC

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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<b>Office Action Summary</b>	<b>Application No.</b> 10/533,827	<b>Applicant(s)</b> DAVIES ET AL.	
	<b>Examiner</b> Annette F. Dixon	<b>Art Unit</b> 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 May 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-33,37 and 38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-33,37 and 38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

1. This Office Action is in response to the amendment filed on May 20, 2008. Examiner acknowledges claims 1-33, 37, and 38 are pending in this application with claim 1 having been currently amended, and claims 34-36 having been cancelled, and claims 37 and 38 having been newly added.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 11, 15, 19-21, 24, 30, 37, and 38 are rejected under 35 U.S.C. 102(b) as anticipated by O'Connor (6,029,659).

As to Claims 1, 37, and 38, O'Connor discloses a holder (10) for dispensing a dispensing container system (11) which is adapted to dispense a quantity of fluid contained therein on movement thereof relative to the holder and further includes a dispensing counter means (40) for counting the number of quantities of the fluid dispensed, the holder having a moulded plastics body with inner and outer surfaces, the inner surface bounding a cavity adapted to receive the dispensing container system (11) in movable relation thereto, the holder having within a cavity having counter advance means (50) adapted in use to cooperate with the dispensing counter means (40) on

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relative movement between the dispensing container system (11) and the body (10) to advance the dispensing counter means (40) to indicate the dispensing of a quantity of the fluid, wherein the body (10) is formed with an outlet port (12) in communication with the cavity such that the fluid dispensed from the dispensing container system (11) is dischargeable therethrough, and wherein an aperture (60) extends through the body (10) from the outer surface to the inner surface in alignment with the counter advance means (40). (Figure 5).

As to Claims 2-4, 11, 15, 19-21, 24, and 30, O'Connor discloses the recited particulars of the counter and advance means, wherein the counter (40) and the ratchet elements of the advance means (50) are utilized to actuate the medicament to the patient and advise the patient of the amount of medicament remaining. (Figure 5).

### ***Claim Rejections - 35 USC § 103***

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 5-10, 12-14, 16-18, 23, 25-29, 31, and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Connor (6,029,659) in view of Rand et al. (WO 98/56444).

As to Claims 5-10, 12, and 23, O'Connor discloses the holder for the dispensing container system, yet does not expressly disclose the orientations of the dispensing

container system. However, at the time the invention was made the use of the structural orientations was known. Specifically, Rand teaches the use of the structural orientations to prevent the rotation of the dispensing container (11). (Figure 2). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of O'Connor to include the retaining means, as taught by Rand to prevent rotation of the dispensing container system within the housing.

As to Claims 13, 14, and 16-18, Rand discloses the outlet port of the holder forms a nozzle for insertion into the nose of a patient (Page 8, Lines 8-11).

As to Claims 22 and 33, Rand disclose a holder for an inhaler comprising all the recited elements, yet does not expressly disclose the use of injection molding. However, at the time the invention was made the use of injection molding in the formation of inhalers was well known for the ability to enable the uniform construction of the device thereby lowering the costs associated with manufacture. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to construction the holder for the inhaler via injection molding as this process enabling higher product production as the Applicant has done.

As to Claims 25-29, 31, and 32, Rand discloses the container (2) has an outlet member (6) and a container member (the region holding the medicament) which contains the fluid and is movable relative to the outlet member to dispense fluid from the outlet member. Further Rand discloses the use of stand (10) to support the container (2) in operation.

### ***Response to Arguments***

6. Applicant's arguments filed May 20, 2008 have been fully considered but they are not persuasive. Applicant asserts the prior art made of record does not disclose or teach a moulded counter advance means wherein the counter advance means is moulded to the holder. Examiner respectfully disagrees with Applicant's assertions. Regarding the moulded counter advance means, it should be noted that the portion of the recitation that claims the moulded counter advance means is directed to a process. Since the claim is an apparatus/product claim, patentable weight is only given to the end product. "Even though process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product by process claim is in the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." *In re Thorpe*, 777 F. 2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985). Regarding the attachment of the counter advance means to the housing, there is no recitation within the claim language that recites that the counter advance means must be molded to the housing. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

### ***Conclusion***

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Annette F. Dixon whose telephone number is (571) 272-3392. The examiner can normally be reached on Monday thru Thursday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Justine R Yu/  
Supervisory Patent Examiner, Art Unit 3771

Annette F Dixon  
Examiner  
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